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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,020	09/15/2000	Jeffery W. Bacher	16026-9267	1823

7590 11/17/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

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DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,020

Applicant(s)

BACHER ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 30-47, 49, 52 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29, 48, 50, 51, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 16) filed on June 19, 2003 has been entered.
2. The IDS (Paper No. 14) filed on April 18, 2003 has been entered and considered.
3. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.16).
4. With reference to the rejection made in the previous office action under statutory double patenting Applicants' arguments are fully considered however, the rejection is withdrawn in view of the abandonment of the application 09/841,366.
5. With reference to the rejections made under 35 USC 102(e), Applicant's arguments and amendment have been fully considered, and the rejection is withdrawn in view of the arguments and new grounds of rejection (Paper No.16).
6. With reference to the rejection made in the previous office action under 103(a), Applicants' arguments and amendment are fully considered and the rejection is with drawn in view of the arguments and new grounds of rejection (Paper No. 16).
7. With reference to the allowable claims, Applicants arguments regarding claim 30 is fully considered and found not persuasive. Claim 30 recites SEQ ID Nos. 5-8, which include non examined SEQ ID Nos. 5-6. If the claim 30 is rewritten reciting SEQ ID No.s 7-8, it would be allowable.

New issues

8. The instant specification is objected because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see at least on page 27, line 6). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-29, 48-54 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15, 17-24, 41-56 of copending Application No.10/ 314, 810. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 10-14, 15-16, 24-28 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. (Oncology Reports, Vol. 6, pp. 497-505, 1999) and in view of Dau et al. (USPN. 6,531,282).

Frazier et al. teach a method of claims 1, 10, 15-16, and 53, for analyzing micro-satellite loci (five loci), the method comprising (a) providing primers for a set of at least three microsatellite loci of genomic DNA (see page 499, column 2, paragraphs 1-2); (b) set of at least three microsatellite loci in a multiplex amplification reaction comprising said primers and producing amplified DNA fragments (see page 499, column 2, paragraph 2); and (c) determining the size of the amplified DNA fragments (see page 499, column 2, paragraph 2). Frazier et al. also teach that the microsatellite loci comprise mono and tetra nucleotide repeat (BAT26, FGA)(see page 497, column 1, abstract, page 499, column 2, table II); at least one oligonucleotide primer for each locus was fluorescently labeled (see page 500, column 2, paragraph 1); sample comprises normal DNA from a patient and DNA originating from a tumor and detection of microsatellite instability by comparing the size of the amplified DNA fragments (see page 501, column 2, paragraph 1, page 502, Figure. 3);

With regard to claims 11-14, 24-28, method comprises correlation between MSI with prognosis and familial tumor predisposition (page 504, column 1, paragraph 4, page 503, column 2, paragraph 3); cancerous tumors were from a colorectal cancer (see page 497, column 1,

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abstract, page 498, column 2, paragraphs 1-2); the tumor sample comprises tumor tissue, blood cells (see page 498, column 2, paragraph 2, page 499, column 2, paragraph 1).

However Frazier et al. did not teach co-amplification of multiple loci.

Dau et al teach a multiplex amplification method to co-amplify short tandem repeat loci (CODIS loci) wherein Dau et al. disclose that the method comprises co-amplification of at least three tandem repeat loci from one or more DNA samples and evaluating the amplified alleles in the mixture by comparing amplified alleles to a size standard (see column 5, lines 20-47). Further, Dau et al. disclose that the method allows three or more loci to be amplified in one tube using a single amplification reaction (see 25, lines 50-67, column 26, lines 50-54, table. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of analyzing micro-satellite instability as taught by Frazier et al. with the method of co-amplification as taught by Dau et al. to achieve an expected advantage of developing an improved multiplex reaction limiting the reaction to a single tube because Dau et al. taught the use of co-amplification of multiple loci in a single PCR reaction vessel and detection in a single electrophoretic channel' (see column 5, lines 38-47). An ordinary practitioner would have been motivated to combine the method of Frazier et al. with the inclusion of the co-amplification step of Dau et al. which would result in a cost-effective single tube method for detecting microsatellite instability in multiple loci at a time.

Conclusion

No claims are allowable.


Any inquiry concerning this communication or earlier communications from the


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examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
November 6, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER